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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Peter M. Bonutti

EXAMINER: Michael H. Thaler

SERIAL NO.: 10/662,923

GROUP UNIT: 3731

FILED: September 15, 2003

DATED: April 13, 2006

FOR: FLUID OPERATED RETRACTORS

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This is an appeal from a Final Office Action mailed on August 3, 2005 in connection with the above-identified application. This Appeal Brief is accompanied by the requisite fees set forth in 37 C.F.R. § 41.20 (b) (2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is General Surgical Innovations, Inc., a wholly owned subsidiary of Tyco Healthcare Group, LP.

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Dated: April 13, 2006


Dana A. Brussel

II. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal and a request for a Pre-Appeal Brief Panel Review were filed on January 17, 2006 for U.S. Patent Application Serial Number 10/743,192, which is a continuation application of the presently appealed application. On March 17, 2006, an appeal brief was filed in connection with the above-mentioned patent application.

Appellant, appellant's legal representative, and/or the assignee of appellant's interest in the above-identified application are not aware of any other related appeals, interferences, or judicial proceedings which may be related to, directly affect, or be directly affected by, or have a bearing on any decision by the Board of Patent Appeals and Interferences in this Appeal.

III. STATUS OF CLAIMS

The instant application was originally filed on September 15, 2003 with one (1) claim. A Preliminary Amendment was mailed on January 7, 2004 that canceled claim 1 and added new claims 2-9. In an amendment mailed on August 16, 2004, dependent claim 6 was canceled and new claims 10-12 were added. On November 30, 2004, an amendment was mailed that canceled dependent claim 10 and added new claim 13. Independent claim 2 and dependent claims 3-5, 7-9, and 11-13 are pending in this application and are involved in this Appeal. Each of these claims stands finally rejected as set forth in the Office mailed on August 3, 2005. An accurate copy of claims 2-5, 7-9, and 11-13 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed on November 23, 2005 indicated that the Reply to the Final Office Action, which was filed on November 7, 2005, had been considered, but did not place the application in condition for allowance.

A Pre-Appeal Brief Request for Review was mailed on February 3, 2006 to present remarks in support of the claims pending in the instant application. A Notice of Decision from the Pre-Appeal Brief Review was mailed on March 14, 2006. According to the Notice of Decision, the application remains under appeal because there is at least one factual issue for appeal. The panel determined that claims 2-5, 7-9, and 11-13 are still rejected.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 2 is directed towards an apparatus having a first tubular member with a first inflatable member disposed on a distal end thereof and a second tubular member with a second inflatable member disposed on a distal end thereof (Specification page 15, lines 11-15). Each of the tubular members has an open proximal end and an open distal end defining a bore therethrough, while each of the inflatable members has an uninflated state and an inflated state. The first inflatable member has an open proximal end and an open distal end defining a first aperture therethrough. The bore of the first tubular member and the aperture of the first inflatable member are configured for receiving a surgical instrument therethrough (Specification page 15, lines 15-17). The second tubular member is configured for receiving the first tubular member and the first inflatable member in the uninflated state. The first and second inflatable members are

longitudinally spaced apart and define a working space therebetween. When the first and second inflatable members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable of capturing body tissue therebetween (Specification page 19, lines 14-23).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following issues are on appeal:

whether the apparatus of claim 2 is obvious over U.S. Patent No. 4,655,746 to Daniels et al. (hereinafter "Daniels") in view of U.S. Patent No. 5,180,367 to Kontos et al. (hereinafter "Kontos"), each of which discloses a catheter device; and

whether the apparatus of claim 13 is obvious over Daniels in view of Kontos, each of which discloses a catheter device.

VII. ARGUMENT

In rejecting the present claims under 35 U.S.C. § 103 (a), the Examiner has misconstrued the art cited against the pending claims.

The patentability of two groups of claims are argued herein: (1) claim 2 that recites an apparatus having a first tubular member with a first inflatable member disposed at its distal end, a second tubular member with a second inflatable member disposed at its distal end, wherein the second tubular member and the second inflatable member are configured to receive the first tubular member and the uninflated first inflatable member, wherein longitudinal movement of the inflated first inflatable member towards the inflated second inflatable member is capable of capturing tissue therebetween; and (2)

claim 13 that recites an apparatus having first and second tubular members, first and second inflatable members that are attached to the respective distal ends of the first and second tubular members, wherein movement of the first tubular member towards the second tubular member is capable of separating a first layer of body tissue from a second layer of body tissue when the first and second inflatable members are in an inflated state.

A. Daniels In View of Kontos Fails To Render Obvious The Recited Apparatus Having First And Second Tubular Members Each With An Inflatable Member Where The Inflatable Members are Capable of Capturing Tissue Between The Inflated Inflatable Members

The Examiner has rejected claim 2 as being obvious over Daniels in view of Kontos. This rejection should be reversed.

Independent claim 2 recites an apparatus having a first tubular member and a second tubular member. Each of the tubular members includes an open proximal end and an open distal end defining a bore through each tubular member. In addition, the apparatus includes a first inflatable member and a second inflatable member, wherein each inflatable member has an uninflated state and an inflated state, and is disposed at the distal end of its respective tubular member. The first inflatable member has an open proximal end and an open distal end defining an aperture therethrough. The bore of the second tubular member is dimensioned for receiving the first tubular member and the uninflated first inflatable member. The first and second inflatable members are longitudinally spaced apart defining a working space therebetween. When the inflatable members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable of capturing tissue therebetween.

Contrary to the arguments made by the Examiner, the claims on appeal are not obvious over Daniels in view of Kontos because Daniels in view of Kontos fails to suggest an apparatus having a first tubular member with a first inflatable member at its distal end, wherein the first tubular member and the first inflatable member are received in a second tubular member with a second inflatable member such that movement of the first inflatable member towards the second inflatable member is capable of capturing tissue therebetween when the inflatable members are in an inflated state.

Daniels discloses a catheter device for delivering fluids to a target region in a vessel of a patient. In particular, the catheter device disclosed in Daniels has an outer catheter tube with a balloon disposed on a distal region of the outer catheter tube in combination with an inner catheter tube having a balloon at its distal end. The balloon of the outer catheter tube is formed by sealing the opposite end regions of a flexible sleeve to spaced distal portions of the outer catheter tube. The balloon of the inner catheter tube has a closed distal end that is attached to the distal end of a guide wire.

As disclosed in Daniels, the guide wire is used to guide the tube and balloon into a blood vessel through the outer catheter tube. Further still, Daniels discloses that the guide wire has a spring that is securely anchored to the distal end of the tube, but allows the guide wire to twist or rotate with respect to the outer tube along its length. Clearly, the spring that is attached to the distal end of the balloon seals the distal opening of the balloon and acts as a pressure boundary, thereby allowing inflation of the balloon. Specifically, the proximal end of the guide wire is attached to a wheel that is rotatably mounted to a manifold at the proximal end of the catheter device for rotating the guide wire. A passageway exists between the inner catheter tube and the outer catheter tube

that is used to transfer fluids from a port on the manifold to a segment of the blood vessel that is isolated between the two balloons of the device.

In the Final Office Action, the Examiner acknowledged that Daniels fails to disclose the inner tubular member and its associated balloon having open distal ends and asserted that Kontos discloses a device having an inner tubular member with an open distal end.

Kontos discloses a catheter device having an outer tubular member with an inflatable balloon attached thereto and an inner tubular member having an inflatable balloon at its distal end, wherein the inner inflatable balloon has an open distal end. The outer tubular member has a lumen for receiving the inner tubular member and its associated inflatable balloon. According to the Examiner, it would have been obvious to make the distal end of Daniels' inner catheter tube and associated balloon open so that they can slidably receive a guidewire. The Examiner argued that the guidewire was a surgical instrument.

However, to establish a *prima facie* case of obviousness under 35 U.S.C. § 103 (a), three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations.¹

In the instant case, modifying the inner inflatable balloon of Daniels to have an open distal end as disclosed in Kontos has no reasonable expectation of success. There is no suggestion to modify a prior art device where the modification would render the

¹ MPEP § 706.02 (j), Eighth Edition, Revision 3, August 2005.

device inoperable for its intended purpose. In re Gordon, 733 F. 2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Furthermore, in McGinley v. Franklin Sports, Inc., 262 F. 3d 1339, 60 USPQ2d 1001, 1010 (Fed. Cir. 2001), the court stated that:

We have noted elsewhere, as a "useful general rule," that references that teach away cannot serve to create a prima facie case of obviousness.... If the references taken in combination would produce a "seemingly inoperative device," we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.

Modifying the inner inflatable balloon of Daniels to have an open distal end as disclosed in Kontos would necessitate the removal of the flexible spring that would eliminate a pressure boundary for the inflatable balloon and the attachment point for the guide wire. Without a pressure boundary at its distal end, the inner inflatable balloon would be incapable of retaining pressurized fluid and would not inflate upon introduction of the pressurized fluid. In addition, without an attachment point for the guide wire, the inner inflatable balloon would not rotate when the guide wire is rotated from the manifold. This modification, as proposed by the Examiner, renders the catheter disclosed in Daniels inoperable for its intended purpose. Specifically, Daniels discloses:

The catheter device is intended for use in transferring fluid material to or from a selected-length segment of a vessel. In practicing the method of the invention, the first catheter is threaded into the vessel of interest until the associated balloon is positioned adjacent one end of the vessel [sic] segment. As part of the positioning procedure, the catheter may be used to deliver a contrast agent for purposes of tissue imaging. The second catheter is then threaded through the first catheter and into the vessel until its balloon is positioned adjacent the other end of the segment. Inflating the two balloons isolates the vessel segment. Fluid is then transferred through the device into or out of the isolated segment.²

As such, the resulting inoperable device cannot suggest the device recited in claim 2 and

² U.S. Patent No. 4,655,746 to Kontos et al. at Column 2, lines 35-47.

the references cannot serve as predicates for a *prima facie* case of obviousness.

Thus, Daniels in view of Kontos fails to render obvious claim 2 and the rejection of claim 2 under 35 U.S.C. 103 (a) should be reversed.

B. Daniels In View of Kontos Fails To Render Obvious The Recited Apparatus Having First And Second Tubular Members Each With An Inflatable Member That Is Capable of Separating A First Layer of Tissue From A Second Layer Of Tissue When The First Tubular Member Is Moved Towards The Second Tubular Member

The Examiner has rejected claim 13 as being obvious over Daniels in view of Kontos. This rejection should be reversed.

Dependent claim 13 depends directly from independent claim 2 and recites an apparatus having a first tubular member and a second tubular member. Each of the tubular members includes an open proximal end and an open distal end defining respective first and second bores therethrough. In addition, the apparatus includes a first inflatable member and a second inflatable member, wherein each inflatable member has an uninflated state and an inflated state, and is disposed at the distal end of its respective tubular member. The first inflatable member has an open proximal end and an open distal end defining an aperture therethrough. The bore of the second tubular member is dimensioned for receiving the first tubular member and the uninflated first inflatable member. The first and second inflatable members are longitudinally spaced apart defining a working space therebetween. When the inflatable members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable of capturing tissue therebetween. Further still, while in the inflated state,

movement of the first inflatable member towards the second inflatable member is capable of separating a first layer of tissue from a second layer of tissue.

Contrary to the arguments made by the Examiner, the claims on appeal are not obvious over Daniels in view of Kontos because Daniels in view of Kontos fails to suggest an apparatus having a first tubular member with a first inflatable member at its distal end, wherein the first tubular member and the first inflatable member are received in a second tubular member with a second inflatable member such that movement of the first inflatable member towards the second inflatable member is capable of capturing tissue therebetween or separating a first layer of tissue from a second layer of tissue when the inflatable members are in an inflated state.

As discussed hereinabove, Daniels discloses a device that delivers fluid to a target region in a vessel of a patient. Daniels specifically discloses that the purpose of the catheter device is for isolating a segment of a vessel so that fluid may be transferred through the device into or out of the isolated segment.³ In furtherance of his stated purpose, Daniels discloses that one inflatable balloon is located immediately proximal to the most proximal vascular branch and the other inflatable balloon is located immediately distal to the most distal vascular branch.⁴ After the balloons are positioned, they are inflated to provide hemostatic sealing, which may be verified by injecting a bolus of contrast material into the sealed region under fluoroscopy.⁵ Contrary to the Examiner's position that movement of the first inflatable member towards the second inflatable member is inherently capable of capturing body tissue therebetween, Daniels fails to

³ *Id* at Column 2, lines 35-47.

⁴ *Id* at Column 5, line 65 - Column 6, line 3.

⁵ *Id* at Column 6, lines 44-50.

disclose or suggest that either of the inflatable balloons should be moved when in the inflated state. As discussed hereinabove, Daniels specifically discloses that the inflatable balloons are inflated at axially spaced locations to isolate a segment of a blood vessel. Moving one inflatable balloon towards the other inflatable balloon would be contrary to Daniels' disclosure about providing a hemostatic seal with the vessel. Rather than disclosing or suggesting moving one inflated balloon towards the other inflated balloon, Daniels specifically discloses (1) the uninflated inner balloon is moved in relation to the uninflated outer balloon during insertion of the catheter device⁶ and (2) the uninflated inner balloon is moved in relation to the inflated outer balloon during removal of the catheter device.⁷ These disclosed operations, in combination with the structural configuration of the catheter device, support one of Daniels' stated objectives to provide "a catheter device designed for transferring fluid material to or from an isolated vessel segment."⁸ Similarly, Daniels states that:

The catheter device is intended for use in transferring fluid material to or from a selected-length segment of a vessel. In practicing the method of the invention, the first catheter is threaded into the vessel of interest until the associated balloon is positioned adjacent one end of the vessel [sic] segment. As part of the positioning procedure, the catheter may be used to deliver a contrast agent for purposes of tissue imaging. The second catheter is then threaded through the first catheter and into the vessel until its balloon is positioned adjacent the other end of the segment. Inflating the two balloons isolates the vessel segment. Fluid is then transferred through the device into or out of the isolated segment.⁹

In order to provide a hemostatic seal and isolate a segment of the vessel, the balloons are shaped so as to engage the wall of the vessel, as seen in Fig. 6. As such, Daniels fails to

⁶ *Id* at Column 6, lines 18-50.

⁷ *Id* at Column 8, lines 13-18.

⁸ *Id* at Column 2, lines 3-5.

⁹ *Id* at Column 2, lines 35-47.

teach or suggest moving an inflated balloon towards another inflated balloon to capture tissue therebetween and separate a first layer of tissue from a second layer of tissue as recited in claim 13. Providing an open distal end for the distalmost balloon, as disclosed in Kontos, does not cure the deficiencies of Daniels.

Thus, Daniels in view of Kontos fails to render obvious claim 13, and the rejection of claim 13 under 35 U.S.C. § 103 (a) should be reversed.

C. Conclusion

In view of the foregoing analysis and remarks, it is clear that the apparatus having a first tubular member having an open proximal end and an open distal end defining a first bore therethrough, a first inflatable member disposed on the distal end of the first tubular member, the first inflatable member having an uninflated state and an inflated state wherein the first inflatable member has an open proximal end and an open distal end defining a first aperture therethrough, the first aperture and the first bore being configured and dimensioned for receiving a surgical instrument therethrough, a second tubular member having an open proximal end and an open distal end defining a second bore therethrough, the second tubular member being configured and dimensioned for receiving the first tubular member and the first inflatable member in the uninflated state, and a second inflatable member disposed on the distal end of the second tubular member, the second inflatable member having an uninflated state and an inflated state, wherein the first and second inflatable members are longitudinally spaced apart to define a working space therebetween, and when the first and second members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable

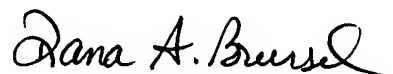
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of capturing body tissue therebetween as recited in independent claim 2 is not rendered obvious by Daniels in view of Kontos. For at least the foregoing reasons, it is respectfully submitted that:

the apparatus of claim 2 is not rendered obvious over Daniels in view of Kontos, and this rejection should be reversed; and

the apparatus of claim 13 is not rendered obvious over Daniels in view of Kontos, and this rejection should be reversed.

Respectfully submitted,

A handwritten signature in cursive script, reading "Dana A. Brussel", written in dark ink.

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VIII. CLAIMS APPENDIX

Claim 2: An apparatus for separating layers of tissue comprising:

a first tubular member having an open proximal end and an open distal end defining a first bore therethrough;

a first inflatable member disposed on the distal end of the first tubular member, the first inflatable member having an uninflated state and an inflated state wherein the first inflatable member has an open proximal end and an open distal end defining a first aperture therethrough, the first aperture and the first bore being configured and dimensioned for receiving a surgical instrument therethrough;

a second tubular member having an open proximal end and an open distal end defining a second bore therethrough, the second tubular member being configured and dimensioned for receiving the first tubular member and the first inflatable member in the uninflated state; and

a second inflatable member disposed on the distal end of the second tubular member, the second inflatable member having an uninflated state and an inflated state, wherein the first and second inflatable members are longitudinally spaced apart to define a working space therebetween, and when the first and second members are in the inflated state, movement of the first inflatable member towards the second inflatable member is capable of capturing body tissue therebetween.

Claim 3: The apparatus of claim 2, wherein the first tubular member further comprises a first inner member disposed with the first tubular member and defining an annular space therebetween, the annular space in fluid communication with the first inflatable member.

Claim 4: The apparatus of claim 3, wherein the second tubular member further comprises a second inner member disposed within the second tubular member and defining an annular space therebetween, the annular space in fluid communication with the second inflatable member.

Claim 5: The apparatus of claim 2, wherein the first inflatable member has a substantially toroidal configuration.

Claim 7: The apparatus of claim 5, wherein the second inflatable member has a substantially toroidal configuration, the second inflatable member having an open proximal end and an open distal end defining a second aperture therethrough.

Claim 8: The apparatus of claim 7, wherein the second aperture is dimensioned for receiving the first tubular member.

Claim 9: The apparatus of claim 7, wherein the second aperture is dimensioned for receiving the first tubular member and a surgical instrument.

Claim 11: The apparatus of claim 2, wherein the surgical instrument is an endoscope.

Claim 12: The apparatus of claim 2, wherein the surgical instrument is a laparoscopic instrument.

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Claim 13: The apparatus of claim 2, wherein movement of the first tubular member towards the second tubular member being capable of separating a first layer of body tissue from a second layer of body tissue when the first and second inflatable members are in the inflated state.

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IX. EVIDENCE APPENDIX

None.

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X. RELATED PROCEEDINGS APPENDIX

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